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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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P.O. BOX 55874 BOSTON, MA 02205			KOSSON, ROSANNE	
BOSTON, MA	02203	ART UNIT PAPER NUMBE		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/688,794	JARDEMARK ET AL.
Office Action Summary	Examiner	Art Unit
	Rosanne Kosson	1652
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with the c	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
<ol> <li>Responsive to communication(s) filed on 14 J</li> <li>This action is FINAL. 2b) This</li> <li>Since this application is in condition for allowated closed in accordance with the practice under the</li> </ol>	s action is non-final. ince except for formal matters, pro	
Disposition of Claims		
4)  Claim(s) <u>1-102</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5)  Claim(s) is/are allowed. 6)  Claim(s) is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) <u>1-102</u> are subject to restriction and/or	wn from consideration.	
Application Papers		
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11.	cepted or b) objected to by the liderawing(s) be held in abeyance. Section is required if the drawing(s) is objected.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority document 2. ☐ Certified copies of the priority document 3. ☐ Copies of the certified copies of the priority document application from the International Bureat * See the attached detailed Office action for a list	ts have been received. ts have been received in Applicati ority documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate

Application/Control Number: 10/688,794 Page 2

Art Unit: 1657

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 1. Claims 1-12, drawn to an electrode comprising a nanotip comprising a diffusion barrier, classified in class 436, subclass 151.
- Claims 13-23, drawn to an electrode comprising two parallel longitudinal lumens and an end designed for contacting biological molecules, classified in class 436, subclass 151.
- Claims 24-31, drawn to an electrode comprising a housing comprising two
  conducting layers separated by an insulating layer and an end designed for
  insertion into a cell, classified in class 436, subclass 151.
- 4. Claims 32-54, 66-76, 78 and 79-91, drawn to a planar substrate comprising a plurality of apertures with electrically conducting tips for inserting into a cell or cell structure and a microfluidics apparatus comprising the planar substrate, classified in class 436, subclass 52.
- 5. Claims 55-65, 67, 71 and 75-91, drawn to a microfluidic system comprising a measurement chamber and a planar substrate comprising at least one aperture with a tip and at least one microchannel with an outlet that opens into the measurement chamber, classified in class 436, subclass 52.
- 6. Claims 92-102, drawn to a method of measuring an electrical property of a cell, comprising the step of inserting an electrode comprising a nanotip comprising a diffusion barrier into the cell and recording the electrical properties of the cell with the electrode, classified in class 435, subclass 4.

Art Unit: 1657

7. Claims 92-102, drawn to a method of measuring an electrical property of a cell, comprising the step of inserting an electrode comprising two parallel longitudinal lumens and an end designed for contacting cells into the cell and recording the electrical properties of the cell with the electrode, classified in class 435, subclass 4.

Page 3

8. Claims 92-102, drawn to a method of measuring an electrical property of a cell, comprising the step of inserting an electrode comprising a housing comprising two conducting layers separated by an insulating layer and an end designed for insertion into a cell into the cell and recording the electrical properties of the cell with the electrode, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-5 are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions 1-3 are drawn to three different electrodes, each of which has a different design, i.e., a different structure. Inventions 4 and 5 are drawn to two different planar substrates and microfluidic devices, neither of which requires the electrodes of Groups 1-3. Each of the planar substrates in Groups 4 and 5 has a different structure, i.e., features that are not present in the other structure. Therefore, these inventions are patentably distinct.

Inventions 6-8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of the different inventions is a method of using a different electrode, each of which has a different structure. Therefore, these inventions are patentably distinct.

Art Unit: 1657

Inventions 1 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the electrode of Group 1 may be used to measure the electrical properties of a small volume of solution to monitor a chemical reaction. Therefore, these inventions are patentably distinct.

Invention 1 and inventions 7-8 are unrelated, because the electrode of Group 1 is not used in the methods of Groups 7-8. Therefore, these inventions are patentably distinct.

Similarly, inventions 2 and 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the electrode of Group 2 may be used to measure the electrical properties of a small volume of solution to monitor a chemical reaction. It need not contact a biological molecule. Therefore, these inventions are patentably distinct.

Invention 2 and inventions 6 and 8 are unrelated, because the electrode of Group 2 is not used in the methods of Groups 6 and 8. Therefore, these inventions are patentably distinct.

Similarly, inventions 3 and 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the electrode of Group 3 may be used to measure the

electrical properties of a small volume of solution to monitor a chemical reaction. It need not be inserted into a cell. Therefore, these inventions are patentably distinct.

Invention 3 and inventions 6-7 are unrelated, because the electrode of Group 3 is not used in the methods of Groups 6-7. Therefore, these inventions are patentably distinct.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above <u>and</u> there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 9 is generic to the following disclosed patentably distinct species: each of the different diffusion barriers listed in the claim.

Claim 35 is generic to the following disclosed patentably distinct species: each of the different conducting media listed in the claim. Claim 36 is generic to the following disclosed patentably distinct species: each of the different conducting media listed in the claim. The elections in claims 35-36 must be compatible. For example, if a liquid conducting medium is elected in claim 35, an electrolyte solution or an electrically conducting polymer (in solution) must be elected in claim 36. If Applicant elects "combinations thereof" in claim 35, Applicant must indicate the number of combinations and the exact composition of each combination in the elected species.

Application/Control Number: 10/688,794 Page 7

Art Unit: 1657

Similarly, claim 58 is generic to the following disclosed patentably distinct species: each of the different conducting media listed in the claim. Claim 59 is generic to the following disclosed patentably distinct species: each of the different conducting media listed in the claim. The elections in claims 58-59 must be compatible. For example, if a liquid conducting medium is elected in claim 58, an electrolyte solution or an electrically conducting polymer (in solution) must be elected in claim 59. If Applicant elects "combinations thereof" in claim 58, Applicant must indicate the number of combinations and the exact composition of each combination in the elected species.

Claim 94 is generic to the following disclosed patentably distinct species: each of the different components of the fluid stream listed in the claim. Applicant must elect either a therapeutic agent or a toxic agent.

The species in the claims listed above are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in each of the claims listed above that corresponds to the elected group (e.g., claim 9 if Group 1 is elected) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected

Art Unit: 1657

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/688,794 Page 10

Art Unit: 1657

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson Examiner, Art Unit 1652

rk/2008-04-16

/Jon P Weber/

Supervisory Patent Examiner, Art Unit 1657